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REMARKS

Claims 1, 3, 5-9, 12 and 25 are pending.

Claims 1, 3, 5-6, 8 and 12 are rejected under 35 USC §112.

Claims 1, 3, 5-7, 9, 12 and 25 are rejected under 35 USC §102 or, alternatively, §103.

Claim 8 is rejected under 35 USC §103.

Claims 6 and 7 have been cancelled without prejudice.

Upon entry of this amendment, Claims 1, 3, 5, 8, 9, 12 and 25 will be pending

Applicants wish to thank the Examiner for reopening prosecution in light of Applicants Brief Pursuant to 37 C.F.R. 1.192, filed August 24, 2004.

Objection to the Specification

The Office Action first objects to the amendment to Page 8 of the specification as introducing new matter into the specification. In response, Applicants have deleted the objected to language and replaced it with the original language. Accordingly, Applicants respectfully submit that this objection has been rendered moot and should be withdrawn.

Rejection under 35 USC §112

The Office Action rejects claims 1, 3, 5-6, 8 and 12, under 35 USC § 112, first paragraph, for failing to comply with the written description requirement by the addition of new matter. In response, while Applicants respectfully submit that the previous language was fully supported by the originally filed specification, to advance prosecution, Applicants have deleted the objected to language from claim 1 and replaced it with language even more clearly supported by the originally filed specification. For example, the newly added language "selected from the group consisting essentially of sodium hydroxide and precursors thereof, potassium hydroxide and precursors thereof, ammonium hydroxide and precursors thereof, magnesium hydroxide and precursors thereof, arginine, cysteine and thymine" is taken from the originally filed specification Page 8, lines 25-28. Applicants note that the current amendment returns this passage to the specification. Further, Applicants have canceled claim 6. Accordingly, Applicants respectfully submit that this rejection has been rendered moot and should be withdrawn.

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Claims 5, 6, 20-22 and 30 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to use the invention commensurate in scope with these claims because the specification does not provide enablement for a composition comprising any newly added neutralizer. Initially, Applicants note that the pending claims do not contain claims 20-22 and 30, and therefore, Applicants are not completely sure which claims stand rejected on this basis beyond claims 5 and 6. Applicants believe that the basis for this rejection is the alleged addition of new matter into the specification and into claims 1 and 6. However, as noted in response to the written description rejection discussed above, claim 1, from which claim 5 depends, has now been amended to delete the allegedly unsupported language and claim 6 has been canceled. Accordingly, Applicants respectfully submit that this rejection has been rendered moot and should be withdrawn.

Finally, claims 1, 3, 5-6, 8 and 12 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action alleges that the phrase "neutralizer designated by the FDA" in claims 1 and 6 is improper because essential material which is not a U.S. patent may not be incorporated by reference into the claims. In response, Applicants have amended claim 1 to delete the allegedly improper phrase, and have canceled claim 6. Applicants respectfully submit that this rejection has been rendered moot and should be withdrawn.

Rejection under 35 USC §§102 and/or 103

The Office Action rejects claims 1, 3, 5, 6, 7, 9, 12 and 25 under 35 USC § 102(b) as being anticipated by, or alternatively under 103(a) as being unpatentable over Samour et al. (US 5,976,566). The Office Action alleges that Samour teaches a topical alcoholic gel containing 55-70% ethanol, isopropanol or mixture thereof, 0-2% cellulosic thickener, and a base to adjust the pH. The Office Action alleges that Samour teaches that sodium hydroxide can be used to neutralize the formulation and the thickener can be carbopol®, a carbomer. The Office Action asserts that Samour teaches the specific viscosity range recited in claim 12, and that one would envisage that the claimed compositions and the composition taught by Samour would have the same viscosity. The Office Action also recognizes that Samour does not teach the antimicrobial activity recited in the preamble or the density recited in the claim. However, the Office Action alleges that these limitations, and the specific viscosity range claimed, would have been inherently possessed by Samour because "all of the ingredients required by the

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claims are also included in the patented composition" and "because all the essential elements required by the instant claims are the same."

Initially, Applicants note that claim 1, and all claims which depend there from, and not only claim 12 as alleged in the Office Action, recites the specific viscosity range "of from about 1,000 to 65,000 centipoise at 70 degrees Fahrenheit. The Office Action initially asserts that this range is taught by Samour, but has failed to cite to any supporting language in Samour for this assertion. The Office Action then asserts that the claimed viscosity range would have been inherently possessed by Samour because one would envisage that the claimed compositions and the composition taught by Samour, having similar ingredients, would have the same viscosity, absent evidence to the contrary.

However, Applicants have previously provided such evidence to the contrary to the Examiner. On April 20, 2004, Applicants submitted the Declaration of Mojgan Cline under 37 CFR 1.132 to the USPTO (a courtesy copy is attached to this response). At paragraph 10-12, Dr. Cline describes measurements taken on two formulations prepared in the manner set forth in Samour. At paragraph 11, Dr. Cline notes that "both compositions resulted in clear, colorless, zero viscosity solution[sic]." (emphasis in original). Again at paragraph 12, Dr. Cline notes that the viscosities of the compositions was "unmeasurable, i.e., zero." Therefore, Applicants respectfully submit that they have previously presented evidence showing that the Samour compositions do not, in fact inherently possess the same viscosity range as that presently claimed. In order for a disclosure to be inherent, "the missing descriptive matter must necessarily be present" in the prior art. *See Continental Can Co. v. Monsanto*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)(emphasis added). In this case, Applicants have presented evidence showing that the claimed viscosity range is absent from the compositions taught by Samour, and thus, are not "necessarily present" as required under the appropriate legal standard. Accordingly, Applicants respectfully submit that this rejection should be withdrawn.

With respect to assertion that the density limitation in the preamble is inherently met by the composition taught in Samour, Applicants initially note that the density recitation is not in the preamble as alleged by the Office Action, but is a limitation of claim 1. Furthermore, Applicants note that the density is defined as the mass of a composition divided by its volume and is a direct function of the components of the composition. The composition taught by Samour contains several additional elements from the claimed aliphatic alcohol, thickening agent and neutralizer, specifically, at least ibuprofen, or other NSAID, and a glycol. As previously noted, the missing descriptor, in this case a density of at least 0.8 g/ml, "must

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necessarily be present" in Samour to inherently anticipate the claimed invention. Applicants assert that given the differences in the ingredients, and their amounts, Samour does not necessarily result in a composition having a density of at least 0.8 g/ml, and thus can not inherently anticipate the claimed invention. Accordingly, Applicants respectfully submit that this rejection should be withdrawn.

The Office Action concludes its rejection in view of Samour by noting that it would have been obvious to one of skill in the art "to modify and employ the claimed viscosity or density . . . in order to determine [the] most effective, stable composition." The Office Action concludes that the variations between the claimed invention and the Samour are "considered to be minor and do[] not render the claims patentably distinct."

Applicants note that the Office Action has failed to set forth a prima facie case for the obviousness of the claims. The Office Action appears to be relying on the "obvious-to-try" standard to reject the claims. However, "obvious-to try" is not the standard under 35 USC § 103. See *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988). The Office Action does not point out where Samour teaches or suggests varying the components until one achieves the critical viscosity and density, or any direction as to which parameters to vary to be successful. As such, it is not a proper rejection of the claims under 35 USC § 103.

For these reasons, Applicants respectfully submit that the rejection of claims 1, 3, 5, 6, 7, 9, 12 and 25 under 35 USC § 102(b) as being anticipated by, or alternatively under 103(a) as being unpatentable over Samour is improper and should be withdrawn.

The Office Action also rejects claims 1, 3, 5, 6, 7, 9, 12 and 25 under 35 USC § 102(b) as being anticipated by, or alternatively under 103(a) as being unpatentable over McKenzie et al. (US 5,747,021). The Office Action alleges that McKenzie teaches a transparent topical composition (e.g. gel) comprising isopropanol, "varbomer" and sodium hydroxide, and that claim 7 of McKenzie recites all of the critical elements required by the pending claims. With respect to claim 12, the Office Action alleges that McKenzie teaches the use of glycerin or PEG-8 for "slip" effect, referring to moisturizers or emollients. Finally, the Office Action alleges that the limitations not explicitly taught by McKenzie, the specific viscosity range and the density, would have been inherently possessed by McKenzie because "all of the essential elements required by the instant claims are substantially the same."

Applicants note that they have previously provided evidence to the Examiner showing that the composition taught by McKenzie does not inherently possess the claimed viscosity range as asserted by the Office Action. On April 20, 2004, Applicants submitted the Declaration of Mojgan Cline under 37 CFR 1.132 to the USPTO. At paragraph 13-18, Dr.

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Cline discusses the teachings of McKenzie and describes measurement taken on a formulation prepared in the manner set forth in McKenzie. At paragraph 18, Dr. Cline notes that "the resulting viscosity was measured at 40 cps." (emphasis added). Therefore, Applicants respectfully submit that they have presented evidence showing that the McKenzie compositions do not, in fact inherently possess the same viscosity range as that presently claimed, but a viscosity well outside the range taught. As noted above, in order for a disclosure to be inherent, "the missing descriptive matter must necessarily be present" in the prior art. (emphasis added). Applicants have presented evidence showing that the claimed viscosity range is not possessed by McKenzie's composition, and, therefore, respectfully submit that this rejection should be withdrawn.

With respect to assertion that the density limitation in the preamble is inherently met by the composition taught in McKenzie, Applicants again note that the density of a composition is defined as the mass of the composition divided by its volume and is a direct function of the components of the composition. The composition taught by McKenzie contains several additional elements, in different quantities from the claimed components, specifically, at least acetylsalicyclic acid (8-22%), glycerin (2-15%), propylene glycol (2-15%) and PEG-8 (1-8%). The missing limitation, a density of at least 0.8 g/ml, "must necessarily be present" in McKenzie to inherently anticipate the claimed invention. Applicants assert that given the differences in the ingredients, and their amounts, McKenzie does not necessarily result in a composition having a density of at least 0.8 g/ml, and thus can not inherently anticipate the claimed limitation. Accordingly, Applicants respectfully submit that this rejection should be withdrawn.

The Office Action asserts that, in view of McKenzie, it would have been obvious to one of skill in the art "to modify and employ the claimed viscosity or density . . . in order to determine [the] most effective, stable composition." The Office Action notes that McKenzie teaches the use of isopropanol, does not explicitly mention ethanol, as recited in claim 3. However, the Office Action asserts that isopropanol and ethanol are "particularly well known alcohols," and that the variations between the claimed invention and the McKenzie are "considered to be minor and do[] not render the claim[] [3] patentably distinct over the prior art of record."

Applicants note that the Office Action has failed to set forth a prima facie case for the obviousness of the claims, and that the Office Action appears to be relying on the "obvious-to-try" standard to reject the claims. As noted above, "obvious-to try" is not the standard under 35 USC § 103. See *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988). The Office Action does

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not point out where McKenzie teaches or suggests varying the components until one achieves the critical viscosity and density, or any direction as to which parameters to vary to be successful. As such, it is not a proper rejection of the claims under 35 USC § 103.

For these reasons, Applicants respectfully submit that the rejection of claims 1, 3, 5, 6, 7, 9, 12 and 25 under 35 USC § 102(b) as being anticipated by, or alternatively under 103(a) as being unpatentable over McKenzie is improper and should be withdrawn.

#### Rejection under 35 USC § 103

Finally, the Office Action rejects claim 8 under 35 USC § 103(a) as being unpatentable over Samour et al. (US 5,976,566) or McKenzie et al. (US 5,747,021) in view of B.F. Goodrich's technical disclosure TDS-237. The Office Action asserts that claim 8 differs from the prior art because it requires a specific neutralizer that contains an amino acid selected from the group consisting of arginine, cysteine and thiamine. The Office Action asserts that B.F. Goodrich teaches that sodium hydroxide is functionally equivalent to arginine containing neutralizer. Thus, it is alleged that an ordinary artisan would have been motivated to do so, with a "reasonable expectation of success because it is always desirable [sic] to have selection option to enhance the efficiency of the manufacturing process and reduce the manufacturing cost due to convenience to obtain ingredients."

Although Applicants disagree with the substance of the rejection of claim 8, Applicants note that it is immaterial to the patentability of claim 8. Claim 8, which depends from claim 1, requires that the resulting composition "has a density of at least 0.8 g/ml, and has a viscosity of from about 1, 000 to about 65,000 centipoise at 70 degrees Fahrenheit." B.F. Goodrich does not teach either of these limitations, which the Office Action admits are not taught by Samour or McKenzie. Accordingly, the Office Action has failed to set forth a prima facie case for invalidity because the combination of the prior art cited does not teach each and every limitation of pending claim 8. Accordingly, Applicants respectfully submit that the rejection of claim 8 under 35 USC § 103(a) as being unpatentable over Samour et al. (US 5,976,566) or McKenzie et al. (US 5,747,021) in view of B.F. Goodrich's technical disclosure TDS-237 should be withdrawn.

#### Conclusion

Therefore, in light of the amendments and remarks made herein, it is respectfully submitted that the rejections under 35 USC §§ 112, 102 and 103 have been overcome. Applicants respectfully submit that they have distinguished the cited art sufficiently to avoid the

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Examiner's rejection. Accordingly, consideration and allowance of Pending Claims 1, 3, 5, 8, 9, 12 and 25 is earnestly solicited.

Respectfully submitted,

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